Cancer Clinical Trials Advisory Council
Meeting Minutes
February 2, 2012
Office of the Commissioner of Securities and Insurance, Helena, MT, and by phone

Council members present
Kristin Page Nei, American Cancer Society Cancer Action Network
Greta Pressler for Marian Diaz, Symetra Life Insurance Company
Dr. Schallenkamp for Dr. Robert Geller, Billings Clinic
Ron Dewsnup, Allegiance Benefit Plan Management
Sharon DeJongh, Bozeman Deaconess Cancer Center
Paul Burns, Cancer Patient
Jo Duszkiewicz, Billings Clinic
Cory Hartman, New West Health Services
Dr. Jack Hensold, Bozeman Deaconess Cancer Center
Dr. Ben Marchello, Frontier Cancer Center and Montana Cancer Consortium
Russ Hill, DOA-Health Care and Benefits Administration
Rachel Peura for Monica Berner, BCBS of MT
Dr. Grant Harrer, Benefis Health System
Michael Foster, Catholic Hospitals
Cori Cook, EBMS
Diane Ruff, Associated Employers Group Benefit Plan & Trust
Brendan Steele, Cancer Patient

Council members absent
Monica Berner, BCBS of MT
Paul Bogumill, Mountain West Benefits
Marian Diaz, Symetra Life Insurance Company
Dr. Robert Geller, Billings Clinic

CSI Staff Present
Christine Kaufmann
Christina Goe
Amanda Roccabruna Eby – Minutes recorder

Public Attendance
Cathy Wilkenson, Billings Clinic
Kathleen Williams
Amber Ireland, Montana Municipal Interlocal Authority

1. **Welcome by Chair, review of agenda, and discussion of deadlines and remaining tasks.**

Chair, Kristin Page Nei, called the meeting to order at 1:03pm. Kristin identified Greta Pressler as an alternate for Marian Diaz. **Ron Dewsnup moved and Cori Cook seconded a motion to accept Greta as Marian's alternate for voting purposes during any meeting Marian is unable to attend. The motion carried unanimously.** The Chair also identified Dr. Schallenkamp as an alternate for Dr. Geller. **Jo Duszkiewicz moved and Ron Dewsnup seconded a motion to accept Dr. Schallenkamp as Dr. Geller's alternate for voting purposes during any meeting Dr. Geller cannot attend. The motion passed unanimously.** It is the Council's policy that alternates attend as often as possible so they are current with the business of the Council.

The Chair reviewed the agenda and the previous meeting's minutes. **Rachel Peura moved and Dr. Ben Marchello seconded a motion to accept the last meeting's minutes. The motion passed unanimously.**

2. **Definitions discussion**

The Chair informed council members on their responses to a survey on the language or the definitions and invited additional responses.

QUESTION 3—Shall we approve the language

‘‘(1) IN GENERAL.—In this section, the term ‘approved clinical trial’ means a phase I, phase II, phase III, or phase IV clinical trial that is conducted in relation to the prevention, detection, or treatment of cancer ~~or other life-threatening disease or condition~~ that is not designed exclusively to test toxicity or disease pathophysiology, that has therapeutic intent, and is described in any of the following subparagraphs:

The yellow highlight is the Medicare language that was added at the last meeting. In the survey since the last meeting, twelve people agreed that the language was accurate to the intent of the motion in the last meeting. **Dr. Ben Marchello moved and Rachel Peura seconded a motion to approve the language for the clinical trial definition. The motion passed unanimously.**

QUESTION 4—Shall we include the language?

‘‘(B) The study or investigation is conducted under an investigational new drug application reviewed by the Food and Drug Administration.

‘‘(C) The study or investigation is a drug trial that is exempt from having such an investigational new drug application.

A Pfizer spokesman and CSI General Counsel thought the sections should be retained. **Jo Duszkiewicz moved and Dr. Jack Hensold seconded a motion to accept the language.** Council members discussed adding more language to this section to include services, supplies, and devices since providers on the council worried the language was not sensitive to the fact that clinical trials include more than just drugs. CSI General Counsel thought that (B) and (C) are meant to specifically cover FDA drugs because (d1) includes the devices and other concerns of the doctors on the council. **The council asked CSI legal counsel to research whether or not services, supplies, and devices are already implied in the earlier section of (d1).** The FDA also approves devices but the council needs to find out more on if devices are actually implied in the d1 language. **The motion passed unanimously to accept (B) and (C).**

QUESTION 5—Shall we include this language?

‘‘(2) CONDITIONS FOR DEPARTMENTS.—The conditions described in this paragraph, for a study or investigation conducted by a Department, are that the study or investigation has been reviewed and approved through a system of peer review that the Secretary determines—

‘‘(A) to be comparable to the system of peer review of studies and investigations used by the National Institutes of Health, and

‘‘(B) assures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review.

Ron Dewsnup moved and Dr. Jack Hensold seconded a motion to accept the language in section (2). The motion passed unanimously.

QUESTION 2 Shall we change the language in this section?

> ORIGINAL‘‘(c) LIMITATIONS ON COVERAGE.—This section shall not be construed to require a group health plan, or a health insurance issuer offering group or individual health insurance coverage, to provide benefits for routine patient care services provided outside of the plan’s (or coverage’s) health care provider network unless out-of network benefits are otherwise provided under the plan (or coverage).

NEW‘‘(c) LIMITATIONS ON COVERAGE.—This section shall not be construed to require a group health plan or issuer to provide coverage for Routine Patient Costs at a higher benefit level than would otherwise be available based on the provider’s network status.

Christina Goe, CSI General Counsel, commented on these language changes. If the purpose adopting a definition of routine care is to produce legislation or provide comments to a future National Association of Insurance Commissioners (NAIC) model law, the council should know that state law can be more protective but it cannot be less protective than federal law. Christina cautioned that changing words can cause problems when trying to conform state law to the minimum federal requirements.

Christina expressed concern about the new wording because it excludes individual plans and would fall below the federal floor. She also warned of the danger in adding too much specificity to a general statute because of the potential for unanticipated circumstances in the future.

Ron expressed concerns about “higher” benefit level rather than the “same.” The importance is that benefits are the same in and out of network. Cori Cook withdrew her objections to the original language. **Ron moved and Ben seconded a motion to accept the original language on limitations on coverage. The motion passed unanimously.**

3. **ERISA regulated self-funded plans**

Overview of ERISA plans by Christina Goe, CSI General Counsel

ERISA is a very broad law from the 1970s that relates to many different employee benefits, including things like pensions, but also relates to health plans that are employer sponsored. State regulation does apply to fully-insured ERISA-regulated health plans, but does not apply to self-funded health plans, except for MEWA’s (multiple employer welfare associations). ACA and HIPPA provisions apply to self-funded ERISA health plans, with some exceptions. Self-funded government plans are not regulated by USDOL or the state insurance department, but many provisions of HIPAA and the ACA do apply to self-funded government health plans.

The NAIC is working on models to incorporate the ACA into state laws, including clinical trials. The new federal law provides an opportunity for the Council to impact federal regulation or guidance, but state models will not apply to single-employer, self-funded health plans. The NAIC could place a more specific definition of routine care in the NAIC model. The council could provide comments to the NAIC committee who is creating model law. The advisory council or the commissioner could also provide comments on clinical trials to the Center for Consumer Information and Insurance Oversight (CCIIO).

External Review – Experimental/Investigational Appeals (although not specifically related to the agenda topic, the council requested information on this topic)

As of Jan 1, 2012 Montana law for external review was preempted in part by federal law. All fully insured and self-funded plans have moved to the federal process outlined in federal regulations. The legislature declined to pass a bill allowing for continued state regulation.

Grandfathered fully-insured plans must still follow existing law on independent medical review. Consumers and providers should call the CSI because it is the federally designated ombudsman and must extend assistance to consumers of self-funded plans as well. Patients can only begin external review once they have exhausted the internal review process. CSI can only assist the consumer or their authorized representative.

External appeals based on medical necessity or a finding of experimental/investigational are reviewed by medical professionals at an Independent Review Organization (IRO). According to the ACA, the federal process for external appeals will be similar to NAIC model act; no specific standards have been set forth yet by the secretary for experimental/investigational review, other than the reference to the model act. The NAIC model provides for specific standards to be used by clinical reviewers who are reviewing a claim that has been denied because it is experimental or investigational. The standards from the model law were distributed to the council members.

Response by Council members

The council asked CSI staff to research the following questions: How does the clinical trials portion of the ACA apply to grandfathered plans? Would this section require those plans to cover clinical trials?

The Council did not make any decisions about recommendations to the Commissioner regarding the need for federal law changes.

4. **Break**

5. **Causes of denial**
   The Council examined a revised document. The Council made several suggestions for format and wording changes. The Chair suggested creating a subcommittee to work through the "causes" document which might be referred to as "Barriers to Access". **Dr. Jack Hensold, Kristin Paige Nei, Jo Duszkiewicz, Dr. Schullankamp, and Cory Hartman volunteered to be on the subcommittee. Kristin agreed to serve as chair.** Kathleen Williams suggested including a findings section in the report to the legislature for things that don't fit into the causes table.

   Kristin asked that everyone take fifteen minutes to review the document again and send Christine anything they would like the subcommittee to review as they proceed to finalize it for the report.

6. **Public comment**
   Kathleen Williams commented that she was observing the proceedings and anticipating the next steps.

7. **Discussion of the final report, possible recommendations, need for legislation**
   The council did not reach any conclusions on possible recommendations. There was discussion about the importance for legislation, if only to incorporate the ACA into state law to allow state enforcement of cancer trial provisions for MEWAs, the state employee plan, and fully-insured plans. The federal government would still have to enforce laws for self-funded, single-employer plans.

   A council member suggested the Council ask the Children and Families committee request and support the legislation and if that fails, that the insurance commissioner should be requested to propose it on behalf of CSI.

Some members expressed interest in a recommendation that the previous draft of external review legislation from the 2011 session proceed again.

Recommendations directed to CCIIO or the NAIC could be included in a final report and sent as public comment. The council might recommend that it to continue to meet to work on legislation or an agreement.

No decisions were made.

8. **Meeting schedule**
   Feb. 28th afternoon
   Mar. 6th afternoon

   Adjournment at 3:58pm